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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/719,272	05/04/2001	Hiroshi Yamamoto	19036/36959	7004

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David A Gass
Marshall O'Toole Gerstein Murray & Borun
6300 Sears Tower
233 South Wacker Drive
Chicago, IL 60606-6402

EXAMINER	
DAVIS, NATALIE A	
ART UNIT	PAPER NUMBER
1642	15

DATE MAILED: 11/20/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Application No. 09/719,272	Applicant(s) YAMAMOTO ET AL.	
	Examiner Natalie A. Davis	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 September 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19,27 and 28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19,27 and 28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement filed 27 August 2001 has been considered. A signed copy is attached hereto.

Applicant's election with traverse of Group I, claims, 1-19 and 27-28 in Paper No. 14 is acknowledged. The traversal is on the ground(s) that the Schlessinger does not teach antibodies specific to LAR. Schlessinger teaches antibodies to epitopes of R-PTPase with approximately 30-50% identity to LAR at the phosphatase domains. This is not found persuasive because antibodies that bind to R-PTPase may crossreact and bind to LAR since the homology of conserved domains are similar. Furthermore, Streuli, et al. disclose antibodies to LAR.

The requirement is still deemed proper and is therefore made FINAL.

Claims -19 and 27-28 are being examined as belonging to the elected Group I, while claims 20-26 and 29-39 are withdrawn from examination as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

1. The specification is objected to and claims 11 and 14 are rejected under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention and failing to provide an enabling disclosure. Even though the specification does provide evidence that the claimed biological materials are (1) known and readily available to the public; (2) reproducible from a written description (e.g. sequenced); or (3) deposited (p.9), the mere reference to a deposit or the biological material itself in any document or publication does not necessarily mean that the deposited biological material is readily available. Even a deposit made under the Budapest Treaty and referenced in a United States or foreign patent document would not necessarily meet the test for known and readily available unless the deposit was made under conditions that are consistent with those specified in these rules, including the provision that requires, with one possible exception (37 CFR 1.808(b)), that all restrictions on the accessibility

be irrevocably removed by the applicant upon the granting of the patent. Ex parte Hildebrand, 15 USPQ2d 1662 (Bd. Pat. App. & Int. 1990).

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 4 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is indefinite in the recitation of "fragment" as the metes and bounds for this component of the polypeptide. There is no indication of size, structure, etc. of the "fragment."

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 4 and 6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polypeptide encoded by SEQ ID NO:1 and a protein, does not reasonably provide enablement for a polypeptide fragment.

6. The claims are drawn to an antibody according to claim 1, which is generated using a polypeptide encoded by SEQ ID NO: 1 or a fragment of the polypeptide as an antigen (claim 4) and further drawn to an antibody generated using a fusion protein comprising a LAR phosphatase domain and another protein or a polypeptide fragment as an immunogen (claim 6).

7. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The specification discloses that polypeptide fragments may be used to generate claimed antibodies. There are many fragments that may or may not perform the same biological functions and the specification does not give any guidance to which fragments will exhibit the biological activities as the claimed. Thus, it would be an undue burden to one of

ordinary skill in the art to assay for fragments encoded by SEQ ID NO: 1 that function as an antigen or a polypeptide fragment as an immunogen, which are capable of generating an antibody as claimed. One cannot extrapolate the teachings of the specification to the scope of the claims because the claims are broadly drawn to any polypeptide and protein fragment and applicant has not enabled all of these types of modifications because it has not been shown that these polypeptides are capable of functioning as that which is being disclosed.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 4-6, 12-13, 15, 19, and 27-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Streuli, et al., (1992).

10. Streuli, et al. (1992) set forth antibodies that bind to LAR Ig and FN II extracellular domains (p. 898), monoclonal antibodies to the 150 kDa protein (designated LAR E- subunit), which is the extracellular portion of LAR and the 85 kDa protein (designated LAR P-subunit), which contains the intracytoplasmic PTPase domains (p. 900-901), and antibodies generated using a fusion protein (LAR-LCA), a hybridoma cell line, and immunization of an animal. The antibodies were screened using the fusion protein from which it was generated to determine specificity to the LAR phosphatase subunit. It is inherent that the antibodies may be encoded by a polypeptide or fragment of SEQ ID NO: 1, and immunoreact with thyroid cancer cells, as Streuli, et al. set forth loss of heterozygosity in the LAR gene of patients with medullary thyroid carcinoma (p. 905). Thus, the prior art reference anticipates the invention as claimed.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 1-10, 12-13, 15-19 and 27-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Streuli, et al., (1988, 1992, and 1990) in view of Furukawa, et al., (1994).

13. Streuli, et al. (1992) teach antibodies that bind to LAR Ig and FN II extracellular domains (p. 898), monoclonal antibodies to the 150 kDa protein (designated LAR E- subunit), which is the extracellular portion of LAR and the 85 kDa protein (designated LAR P-subunit), which contains the intracytoplasmic PTPase domains (p. 900-901), and antibodies generated using a fusion protein (LAR-LCA), a hybridoma cell line, and immunization of an animal. The antibodies were screened using the fusion protein from which it was generated to determine specificity to the LAR phosphatase subunit. Streuli, et al. further set forth loss of heterozygosity in the LAR gene of patients with medullary thyroid carcinoma (p. 905). Streuli, et al. does not teach antibody having specificity to an intracellular domain of a LAR phosphatase subunit.

14. Furukawa, et al. teach antibodies to GST-LAR fusion proteins, CD45 as a transmembrane protein-tyrosine phosphatase that is expressed on all leukecytes and is required for T- and B-cell activation (p. 10928), and antibodies to a fusion protein that was produced by culturing E. coli transformed with an expression vector comprising a coding region of a GST gene and a LAR domain. Furukawa, et al. does not teach an antibody to an intracellular domain of a LAR phosphatase subunit.

15. Streuli, et al. (1990) show that the first of two domains within the cytoplamic (intracellular) region of the receptor linked PTPases of LAR has enzyme activity and that one cysteine residue is required for activity. Streuli, et al. does not teach an antibody to an intracellular domain of a LAR phosphatase subunit.

16. Streuli, et al. (1988) teach the polypeptide encoded by the sequence set out in SEQ ID NO:1, but does not teach an antibody to the sequence.

17. Since Streuli, et al. teach a polypeptide encoded by SEQ ID NO:1, antibodies specific to LAR and how to generate them using fusion proteins and Furukawa, et al. teach GST-LAR fusion proteins, it would have been prima facie obvious to a person of ordinary skill in the art at

the time the invention was made to combine the teachings to make an antibody as claimed. One of ordinary skill in the art would have been motivated to make an antibody specific to the intracellular domain of LAR because PTPases are known to be important in the regulation of cell proliferation, the phosphatase domain is located in the intracytoplasmic PTPase domain (Streuli, et al., 1992), which is the region required for activity (Streuli, et al., 1990). Furthermore, one would be motivated to make an antibody without specificity to CD 45 since it is required for T- and B-cell activation (Furukawa, et al.) and because of the reasonable expectation of success based on well known and accepted methods in the art of how to make antibodies as taught above. One would be motivated to make an antibody from a GST-LAR fusion protein and to purify it using a glutathione support, since it is a well-known method in the art as taught by Furukawa, et al.. Furthermore, one would be motivated to generate the antibody of claims 10, 12-13, and 15-18 because the method is well-known in the art as taught by Streuli, et al. and Furukawa, et al..

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie A. Davis whose telephone number is 703-308-6410. The examiner can normally be reached on M-F 8-5:30 (every other Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4315 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Natalie Davis, PhD
November 16, 2001

GEETHA P. BANSAL
PRIMARY EXAMINER